

K081374 # 12

SEP 09 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the CHARLOTTE™ LisFranc Bone Screw and CHARLOTTE™ LisFranc Plate.

Submitted By:	Wright Medical Technology, Inc.
Date:	May 5, 2008
Contact Person:	Sarah Holtgrewe
	Regulatory Affairs Specialist
Proprietary Name:	CHARLOTTE™ LisFranc Bone Screw
	CHARLOTTE™ LisFranc Plate
Common Name:	Bone Screw
	Fixation Plate
Classification Name and Reference:	21 CFR 888.3040 Screw, Fixation, Bone—Class II
	21 CFR 888.3030 Plate, Fixation, Bone—Class II
Device Product Code and Panel Code:	Orthopedics/87/HRS
	Orthopedics/87/HWC

DEVICE INFORMATION

A. INTENDED USE

The CHARLOTTE™ LisFranc Bone Screw is intended to be used for fixation such as: LisFranc arthrodesis, first metatarsophalangeal arthrodesis, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

The CHARLOTTE™ LisFranc Plate is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

K08137M #212

B. DEVICE DESCRIPTION

The CHARLOTTE™ LisFranc Bone Screw is offered in 2 diameters and a range of lengths to accommodate variability among patients. All screws are made from stainless steel.

The CHARLOTTE™ LisFranc Plate consists of plates, non-locking screws, and locking screws. All components are manufactured from stainless steel.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the CHARLOTTE™ LisFranc Bone Screw and the CHARLOTTE™ LisFranc Plate are substantially equivalent to the design features of the predicates identified in this 510(k) submission. The safety and effectiveness of the CHARLOTTE™ LisFranc Bone Screw and CHARLOTTE™ LisFranc Plate are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 09 2008

Wright Medical Technology, Inc.
% Ms. Sarah Holtgrewe
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K081374

Trade/Device Name: CHARLOTTE™ LisFranc Bone Screw & CHARLOTTE™ LisFranc Plate

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: HRS, HWC

Dated: August 28, 2008

Received: September 3, 2008

Dear Ms. Holtgrewe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Ms. Sarah Holtgrewe

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081374

Device Name: CHARLOTTE™ LisFranc Bone Screw & CHARLOTTE™ LisFranc Plate

Indications For Use:

The CHARLOTTE™ LisFranc Bone Screw is intended to be used for fixation such as: LisFranc arthrodesis, first metatarsophalangeal arthrodesis, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

The CHARLOTTE™ LisFranc Plate is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Prescription Use xxx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DNL
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

1 of 1

510(k) Number K081374